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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHAY, DAVID M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,408	WILL, BRIAN R.	
	Examiner	Art Unit	
	david shay	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 25,2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2009 has been entered.

Regarding the newly amended language in the claims, applicant asserts that this language clarifies what is claimed. The examiner must respectfully disagree. In the interview summary included in the instant response, applicant stated that the recitation of a "concave bottom surface" renders the claims more definite. However, there are several problems with this added language. Firstly, when the meaning to be ascribed to the term "convex" (the term "convex" appears five times in the originally filed disclosure, once in the Abstract; once each in original claims 1 and 11; and twice in the Specification at page 6, line 8 and page 7, line 14) was questioned, the examiner noted that applicant had provided no specific definition to the term "convex" in the originally filed disclosure, but that this term appeared to in actuality appeared to indicate a concave surface (see the office action mailed April 11, 2007, page 14), this view was in part due to the specific recitation in the originally filed disclosure, wherein in the Specification, applicant chose to refer to the "convex bottom contact portion" as element 14 in the drawings, as can readily bee seen from the originally filed drawings, specifically Figures 3 and 4, element 14 clearly indicates the actual surface that contacts and forms a seal with the eyeball. As most readily seen from Figure 4, this surface is indisputably concave, under the usual and customary meaning of the term "concave". In response to the examiner's notification that using the term "convex" in reference to this surface designed to mate with the eyeball,

seemed to indicate that the term "convex" was being used to indicate a configuration which was in fact concave, and that a definition in the specification was required to support an uncommon meaning for a term, applicant instead of providing such a definition, or changing the term to read "concave" so as to be in concert with the usual and customary definition of this term, chose to argue that "a convex surface may be considered concave fron the reverse perspective, so they are not mutually exclusive. The eyeball is essentially a ball – not perfectly spherical – i.e. convex. The eye fixation apparatus described in the application includes an 'annular convex portion' - - i.e. annular to include an opening for access by a surgeon, and convex to match the convex contours of the eyeball. It necessarily follows that the inside of a convex annulus will be concave – it is merely a matter of reference point. So reference to convex in this context, with reference to the eyeball, the Specification, the drawings, and the knowledge of one of ordinary skill in the art, obviously would understand that one could refer to the overall shape as convex or concave and render the same meaning." (see the response filed April 16, 2008, the paragraph spanning pages 10 and 11, beginning at the third sentence thereof). So essentially, applicant has argued that the terms can be used interchangeably. Now, however, applicant has added a claim limitation including the term "concave" – a term which does not appear in the originally filed disclosure, and thus no special definition of the term "concave" can be derived therefrom. This does not serve to further reduce issues of indefiniteness. Is one of ordinary skill in the art to interpret the term "concave" in this recitation as actually meaning "convex", as specifically argued on the record by applicant? And if so, which meaning of "convex" is to be ascribed to the term "concave"? Should one of ordinary skill in the art use the meaning that the originally filed disclosure appears to imply – i.e. concave, or the usual and customary meaning – i.e.

convex? The examiner is hard pressed to understand in what way this simplifies the issues and makes the claims more definite, especially in view of applicant's new stance on the issue of the meanings of these two terms, as articulated in the last full sentence on page 13 of the instant response: "Specific support is also found in Figs 1, 3, and 4, clearly showing a contact portion which is convex from the outside, but which therefore includes a concave interior surface which conforms to the shape of the eyeball", which apparently is now arguing the terms as antonyms, rather than synonyms, as argued in the April 16, 2008 response. Thus would greatly appreciate applicant's guidance on this matter.

Continuing, applicant makes reference to the two Affidavits filed January 16, 2007 and April 16, 2008, the examiner hereby incorporates by reference the full responses to these affidavits set forth in the office actions mailed April 11, 2007 and July 11, 2008, respectively as if reproduced in their entirety.

Concerning the term "low profile" applicant argues that this term refers to the tapered edge of the fixation ring. This rejection has been withdrawn in view of this argument.

Regarding the rejections under 35 U.S.C. 103(a), applicant argues that the examiner has engaged in improper hindsight, as evidenced by "conclusory statements" such as "would be obvious to one of ordinary skill in the art" (see the instant response, page 35, last full sentence); not demonstrated " how a person of ordinary skill in the art would have been motivated to modify the reference to achieve the invention without the benefit of hindsight" (see the instant response, page 34, last sentence); and denied affidavit evidence "without citation to reference or submission of an affidavit himself" (see the instant response, page 34, first sentence). The examiner respectfully disagrees with applicant's assertions, noting that specific reference to the

obviousness of the employment of a particular configuration which produces no unexpected result. Instead of providing evidence of an unexpected result, applicant chose to submit an affidavit which alleged inoperability of the devices disclosed in the references. However, as the references are US patent documents, which specifically claim these devices as arresting movement of the eye, the simple statement of doubt with regard to their functionality by the inventor himself is simply not sufficient evidence upon which to base a conclusion of inoperability of a device claimed in an issued patent, especially when it is not at all clear, that the devices referred to in the affidavit are the actual embodiments the examiner is relying on to support the rejection (see e.g. the office action mailed July 11, 2008, page 3, first paragraph), and wherein despite the examiner's express request for clarification on this point (*Ibid.*), applicant has remained resolutely silent. Instead, applicant has asserted that the examiner must prove that the prior art devices "work exactly the same as applicant's claimed invention". This is not the basis upon which the claims are to be analyzed, in view of applicant's express statement that applicant "does not argue any of the pending claims as means- or step-plus function claims" (see the instant response, page 14, first full paragraph). Claims should not be analyzed with regard to their function, if the claims are expressly stated as not being cast in a format wherein the function of the claim defines the patentable invention. However, even if this were necessary, it is clear from applicant's disclosure of the manner in which the claimed invention operates: "communication with the vacuum port 18 for providing vacuum suction to the eye globe conjunctiva attached to the sclera. When placed on the eye, with the contact portion 14 contacting directly upon the eye and encircling the cornea, the criss-crossing channels 16 are upon the eye globe conjunctiva. Vacuum port 18 communicates with is channels 16 such that

vacuum pressure exerted at the vacuum port 18 creates vacuum pressure in the criss-crossing channels 16, sucking the eye globe conjunctiva attached to the sclera flush against the contact portion 14. This fixates the eye. The criss-crossing channels 16 work to oppose the suction created by each other, such that the eye glove conjunctiva attached to the sclera, is spread taut between the channels 16, instead of being sucked upon into a particular channel. The criss-crossing channels 16 spread the pressure differential created by the vacuum across the eye globe creating a balanced substantially uniform pressure differential, thus avoiding deformation of the eye globe conjunctiva and sclera in the particular channel." (see the originally filed disclosure, the paragraph spanning pages 6 and 7), that the devices of Hellancamp and L'Esperance would function similarly.

Turning to the reference, applicant reasserts the inoperability of the prior art references, noting with respect to L'Esperance that it is applicant's opinion that the porous surface thereof would produce clogging. However, this is merely an opinion, and while rendered by an experienced practitioner, apparently does not rest on any actual experience, but applicant's assessment of what the L'Esperance reference would teach one of ordinary skill in the art. In order for this top be the case, one of ordinary skill in the art would have to be presumed to have a sufficiently low level of skill, that one of ordinary skill in the art would not realize that the openings in the porous membrane of L'Esperance would need to be made large enough to prevent being clogged by the mucus. However, this knowledge cannot be absent from one of ordinary skill in the art, since applicant provides no sizes for the channels of the instant device in the originally filed disclosure, which would also be prone to draw up mucus and thus be clogged thereby. Given that there is a strong presumption of adequate written description in the case of

originally filed claims, (MPEP 2163(I)(A)), if this knowledge were not commonly known to one of ordinary skill in the art, the proper dimensions of the criss-cross channels to enable the device to actually work would be beyond the grasp of one of ordinary skill in the art, and the claims would not be adequately supported. Similarly, if this knowledge is present, the configuring the pores in the membrane of L'Esperance to be of the proper dimension so as not to be clogged by mucus is well within the scope of one of ordinary skill in the art. Applicant also argues that the device of Hellencamp would draw the tissue up into the suction chamber. The examiner must respectfully disagree. It is the examiner's view that the insert of Hellencamp blocks off the entrance to the suction chamber and therefor prevents the eye tissue from protruding thereinto. In fact Hellencamp himself describes the insert's functioning: "[a]s such the material functioning of segment **45**, along with the engagement of its top and bottom edges **46, 48** with the positioning segment **20** prevents inward buckling as the cornea of the eye bulges upwardly" (see Hellencamp, column 9, lines 14-16, emphasis in original). Thus clearly the device of Hellencamp is designed to prevent the conjunctiva from being sucked into the device. Again, the examiner notes applicant has eschewed the reading of the claims under 35 U.S.C. 112, sixth paragraph. Next applicant argues that in Hellencamp the "vacuum ring insert is intended to prevent complete occlusion, not to prevent damage such as chemosis" (instant response, page 44, second sentence of the first full paragraph). However, chemosis is not really the issue here. Hellencamp specifically states that "Any such suction enhancement assembly would preferably provide a suction force substantially about the girth of the eyeball, if not entirely thereabout, instead of to a single point adjacent the eyeball, and further would be structured to apply the suction force about the eyeball in a dispersed and uniform manner" (Hellencamp column 4, lines

23-28). Interestingly, this is also applicant's aim: "so long as the configuration allows the pressure differential to be spread substantially uniform across the contact portion in relation to the eye glob (sic, globe)" (see the originally filed disclosure, page 7, first full paragraph). Thus it is unclear how applicant, absent some showing of unexpected result flowing from the criss-cross nature of the channels, can assert the non-obviousness of the claimed subject matter in view of the the knowledge of one of ordinary skill in the art and the prior art.

In both L'Esperance and Hellencamp, the prior art has demonstrated the desire to modify the eye contacting portion of the suction ring in a manner which further distributes the vacuum force applied to the eye, this is expressly stated on Hellencamp, thus it is a recognized problem in the art. As recognized by the Supreme Court "A person of ordinary skill is also a person of ordinary creativity, not an automaton." KSR International Co. v Teleflex Inc. 82 USPQ2d 1385, 1397 (Supreme Court, 2007) and given the level of skill in the art established in the prosecution history, the lack of any showing or even any attempt to show unexpected results, and the express statement that the channels "Those skilled in the art will know that the criss-crossing channels 16 can be configured in many different ways to create a substantially uniform pressure differential across the contact portion 14 in relation to the eye globe. Criss-crossing channels can be configured as seen in FIGS. 3 and 4. Criss-crossing channels can be configured as parallel radial grooves with cross channels forming a "train track" like design, as multiple radial grooves with cross channels, as multiple interlocking cross-crossing channels, etc., so long as the configuration allows the pressure differential to be spread substantially uniform across the contact portion in relation to the eye glob (sic, globe)" (see the originally filed disclosure, page 7, first full paragraph), absent an unexpected result flowing from the claimed invention, given the

knowledge of one of ordinary skill in the art, and the teachings of the prior art, the particular configuration of the channels is merely a matter of choice.

Continuing, applicant argues that both L'Esperance and Hellencamp "do not disclose means for fixing an eye for surgery other than a hollow annulus" (see the instant response, page 44, last paragraph), and asserts that the hollow annulus has specific disadvantages associated with it, however, applicant fails to explain how these disadvantages are present in the L'Esperance and Hellencamp devices, given that the hollow annulus is blocked off by the insert of Hellencamp and the porous membrane of L'Esperance, respectively.

Further, applicant asserts that the examiner has indicated that certain evidence was provided to address the examiner's "skepticism that prior art devices caused complications in surgery", referring to the office action of April 11, 2010. The examiner respectfully submits that applicant has misconstrued his meaning. The office action of April 11, 2007 clearly states that "affiant nowhere expressly stated that affiant has had any actual experience with this particular type of eye fixation device, this state of affairs is confirmed by affiant's use of the subjunctive in succeeding subsections of this paragraph". Yet, in the succeeding affidavit, rather than asserting that affiant has had "real world" experience with suction rings as set forth in the embodiments of L'Esperance and Hellencamp applied to the claims, merely provided articles article which do not specifically describe the suction rings which were the problem, nor was there any affirmation in the affidavit that the types of rings discussed in the articles had any structure which completely covered the opening of the annular space, as the devices of L'Esperance and Hellencamp.

Next applicant asserts that the instant "rejections appear to be based on a view the Applicant is required to prove that the references cited by the examiner are non-functioning" (see

the instant response, page 45, first sentence of the first full paragraph). This is not so, the rejections are based on the teachings of the prior art in conjunction with the knowledge of one of ordinary skill in the art at the time of the invention. The only reason the issue of the functionality of the references has come up, is because of applicant's vague assertions that the embodiments of the devices taught by the prior art which are applied to the claims do not work. Yet despite repeated urgings on the part of the examiner to make the record more clear concerning the particular structure of the prior art applicant is asserting does not work, applicant has refused to respond to these entreaties and simply submitted more assertions regarding devices, the structure of which is unclear or unknown.

Continuing, applicant asserts that the hollow annulus designs require the use of lid specula, as opposed to applicant's "low profile" design, which does not. However, applicant has not addressed the fact that the protruding membrane portion of the L'Esperance device and the suction ring of Curtain, which has a sloped side constitute "low profile" devices, within the broadest reasonable interpretation of this term, as well. The examiner can find no place where affiant has attributed the problems associated with the prior art "high profile" devices arises from the use of a hollow annulus. The problem has been cast as a result of the abrupt slope (i.e. straight up and down) that constitutes the entire profile of many prior art suction rings.

Further applicant argues that Hellencamp "specifically acknowledges that the cornea is displaced into the hollow vacuum ring to contact the surface of the vacuum enhancer", citing column 9 thereof. The examiner has reviewed the Hellencamp reference, particularly the cited lines in column 9 and has found no such "specific acknowledgement", the examiner has found, however, a specific statement that the "suction enhancement assembly **40** is additionally

structured and disposed to engage the positioning segment so as to define a suction channel **42** between the positioning segment **20** and the suction enhancement member **44**" (column 8, lines 23-27, emphasis in original), which clearly defines the suction channel (or annular vault as applicant terms it) as existing between the housing of the device and the suction enhancement member thus the suction enhancement member cannot be properly described as inside this structure. Similarly, with the L'Esperance device, this porous membrane is situated below the bottom of the annular channel, and thus cannot be considered to allow the eye tissue to be sucked into the annular space.

Next applicant argues that the sponge of L'Esperance cannot be considered to have lands and grooves, the examiner notes that this terminology is also absent from any of the claims. Then applicant asserts that the examiner has "cited nothing in L'Esperance or any other reference suggesting special properties which render L'Esperance's porous membrane not subject to clogging" (see the instant response, page 49, fourth sentence of the paragraph bridging pages 49 and 50). The examiner has in fact done so above: the knowledge of one of ordinary skill in the art, which would enable one of ordinary skill in the art to make the pore size of the porous membrane large enough to prevent clogging. And as also mentioned above with respect to this, applicant has provided no special properties of the vacuum opening which would render it subject to not clogging, in a similar manner to the clogging discussed with regard to the Hellencamp device, which applicant has pointed out on numerous occasions is subject to clogging.

With regard to the statement from the office action mailed June 14, 2007, the assertion in the subsequently filed affidavit could not have been predicted or responded to by the examiner

before the fact. If applicant would care to identify situations wherein the examiner "disputes facts" **after** they have been set forth in an affidavit, the examiner will gladly do his best to respond to these situations. Regarding the argument asserting that the membrane of L'Esperance "would conduct vacuum only through its plane, not laterally, the examiner sees no evidence for this in the L'Esperance reference. The membrane is described as a "wall 23 of air permeable material" there is no requirement that the material "conduct vacuum only through its plane" as asserted by applicant. Further this limitation is also entirely absent from the claims. Regarding the absence of "a flush-mounted land and groove contact surface" in Hellencamp, this feature being similarly absent from the claims, does not serve to define the claimed invention over the applied art.

Regarding the allegation that the prior art applied teaches away from using lid specula, applicant argues that these require "the use of specula causing greater discomfort for patients" and referencing paragraph 8 of the first Will affidavit. Firstly, it is noted that paragraph 8 of the first Will Affidavit does not mention the use of specula with prior art devices, it merely states that the specula are not needed "in most cases" with the low profile device, so affiant has asserted that specula are used with the low profile devices, too. Regarding the "teaching away" of L'Esperance, applicant asserts that because L'Esperance ('148) discusses the use of specula (nowhere does it mention that they are required) it teaches away from not using them. It is unclear to the examiner how a single mention of the use of specula "or other eye-contacting retainer means" (which, incidentally could be the low profile suction ring of L'Esperance ('148)) in L'Esperance ('148) constitutes any teaching away of the concept of not using specula. Next applicant argues that "criss-cross channels with alternating lands and grooves, a recited element

in all claims" eliminates the need for annular vaults, thereby creating as lower profile device" (see the instant response, page 52, the third to the last sentence of the last full paragraph). The examiner respectfully notes that the term "lands and grooves" is entirely absent from all the claims, and further points out that the term "lands" also lacks positive antecedent basis in the originally filed disclosure. Still further, the low profile device is created by the portion that allows the suction ring to fit under the lids (see the originally filed disclosure, page 3, lines 9-10), thus the membrane extending beyond the suction ring wall in L'Esperance ('148) would do so as well.

With regard to the reduction of IOP, the examiner notes that the passage cited in Hellencamp purportedly supporting applicant's assertion that Hellencamp teaches that increased IOP is desirable, merely states that the vacuum is transferred efficiently ("maintains flow-through-integrity") there is no mention of the level of vacuum either in an absolute or relative (to other instruments in the art) sense.

As for the "personal knowledge" referred to by applicant, the examiner notes that no personal knowledge has been relied upon, thus no affidavits are necessary.

Regarding the rejection of claim 12, it is the examiner's view that at least the device of L'Esperance does not draw the conjunctiva into the annular chamber, as can readily bee seen from the illustration of the device situated on the eye. Thus this argument is not convincing. The issue of clogging has been discussed above and will not be repeated here.

With regard to the implication that Affiant explained that "apparatus using the annular vacuum rings of Hellencamp or the annular chamber and porous membrane of L'Esperance prevent the discontinuance of vacuum and repositioning of the fixation apparatus" (see the

instant response, page 55, first full paragraph, emphasis omitted). The examiner respectfully notes that nowhere does Affiant discuss any of the prior art devices used by Affiant as having a porous membrane. This was brought to applicant's attention In the office action mailed April 11, 2007 (see pages 8-9 thereof), yet despite the fact that another Affidavit was filed, there is still no positive statement by Affiant on the record that Affiant has actually used a fixation ring with a porous membrane as taught by L'Esperance. As such the statement by applicant's counsel, rather than a statement in an Affidavit from applicant himself, cannot take the place of evidence (see MPEP 716.01(II)) and is not convincing.

Concerning claims 2 and 13, applicant argues that Curtin does not teach adjusting rods. It is the examiner's view that adjusting rods are taught by Curtin. Elements 14, 28, 34and 128 are all considered to be "adjusting rods" within the broadest reasonable interpretation of this term. These rods are all coupled to (or connected to) the fixation ring through various linkages. While Affiant did note several advantages to the adjusting rods illustrated in the figures of the originally filed disclosure, the claimed structures are far broader than those illustrated.

As to claims 3, 4, 7, 8, 14, 15, 18, and 19, while applicant disagrees with the examiner's assertion that the adjusting that the examiner's determination that Clark et al teach employing X- and Y-axis adjustment mechanisms. The examiner must respectfully submit that Clark does in fact teach X and Y axis adjustments (see column 4, lines 34-51 and column 5, lines 7-23).

Regarding claims 3 and 14 in particular, applicant argues "the mere ability to move through space does not render obvious a structure including guide members connected to an eye fixation apparatus" (see the instant response, page 57, last sentence). However, as Curtin teaches guide members connected to an eye fixation apparatus, this does render the claimed invention

obvious. Continuing, applicant argues that the claims are drawn to annular X and Y translation members. The examiner submits that the blocks having holes therein constitute "annular members" within the broadest reasonable interpretation of the term, as annular is defined as "ring shaped" and as rings can have square or rectangular cross-sections, these elements are considered to be annular.

Concerning claims 7 and 18 in particular, the arguments set forth with regard to claims 3 and 14 are repeated. As to claims 4, 8, 15, and 19, applicant argues that the examiner's explanation of how adjustment screws work does not render the claims obvious. However, it is the examiner's view that the explanation and well known character of adjustment screws, combined with the teachings of the prior art references, does render the claims obvious. Regarding claim 16, as Curtin teaches tightening a screw (e.g. element 36, Figure 1) to secure an object (e.g. element 38, Figure 1) within an annular translation guide member (e.g. element 32, Figure 1), there is no need for Clark to do so as well. As for claims 5, 6, 9, 10, 17, and 20-22, applicant's acknowledgement of the teachings in Olsen is noted, given that the other combined references read on the claims from which these claims depend, these claims are properly rejected. With regard to claim 22, as set forth above, the protruding portion of the membrane is considered to render the device of L'Esperance a "low profile device" similarly, the device of Hellencamp combined with that of Curtin, with its sloping sides, at least a portion of which can fit beneath the eyelid is also considered to constitute a "low profile device" within the broadest reasonable interpretation of the term. Lastly, with respect to claims 12-21

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A term used in the claims may be given a special meaning in the description. No term may be given a meaning repugnant to the usual meaning of the term. Accordingly, MPEP §§ 706.03(d) and 2111.01(IV), some of which is reproduced below, dictates the manner in which the claims have been examined.

Terminology Used Inconsistent with Accepted Meaning

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "convex" in claims 1 and 11 is used by the claim to mean "concave", while the accepted meaning is "curved or rounded like the exterior of a sphere or circle". The term is indefinite because the specification does not clearly redefine the term.

IV. < APPLICANT MAY BE OWN LEXICOGRAPHER

An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning) (quoting Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings"). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." Multiform Desiccants Inc. v. Medzam Ltd., 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) and MPEP § 2173.05(a). The specification should also be relied on for more than just explicit lexicography or clear disavowal of claim scope to determine the meaning of a claim term when applicant acts as his or her own lexicographer; the meaning of a particular claim term may be defined by implication, that is, according to the usage of the term in >the< context in the

specification. See Phillips v. AWH Corp., *>415 F.3d 1303<, 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc); and Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996). Compare Merck & Co., Inc., v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1370, 73 USPQ2d 1641, 1646 (Fed. Cir. 2005), where the court held that patentee failed to redefine the ordinary meaning of "about" to mean "exactly" in clear enough terms to justify the counterintuitive definition of "about." ("When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description.").

Similarly the term “concave” is also unclear, since it is normally construed as the antonym of the term “convex”, however, applicant has argued that these terms can mean the same thing, thus whether the term “concave” which does not appear anywhere in the originally filed disclosure, is to be interpreted with its usual and customary meaning, or with the meaning of the term “convex”, and if the latter which of the meanings argued in the response of April 16, 2008 of the term “convex” should be construed as “concave” are not clear.

Claims 1, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over L’Esperance (EP ’127) and the admitted prior art of the proper positioning of the corneal flap being critical for refractive surgery. L’Esperance (EP ’127) teaches a device and method as claimed except for the criss-cross passages. It would have been obvious to the artisan or ordinary skill to employ criss-cross channels in the devices and methods of L’Esperance (EP ’127), since this is another configuration that would serve to distribute the vacuum force, and is merely a difference of degree, rather than kind, and thus provides no unexpected result, and to discontinue the vacuum and reposition the apparatus if it is not centered on the cornea, since

proper positioning of the corneal flap is critical for refractive surgery, thus producing a device and method such as claimed.

Claims 1, 2, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in combination with Curtin and the admitted prior art of the proper positioning of the corneal flap being critical for refractive surgery. Hellenkamp teach a device and method as claimed except for the criss-cross passages. Curtin teaches the use of adjustment arms on eye fixation devices and a fixation ring which is sloped and therefore considered to be "low profile" as claimed. It would have been obvious to the artisan or ordinary skill to employ criss-cross channels in the devices and methods of Hellenkamp, since this is another configuration that would serve to distribute the vacuum force, and is merely a difference of degree, rather than kind, and thus provides no unexpected result, to employ adjustment arms on the device of Hellenkamp, since these can be used to adjustably position the device, which is necessary due to the fact that eyes of different individuals will be in different relative locations, or alternatively to employ the insert of Hellencamp in the device of Curtin, since this would mitigate problems associated with chemosis, as taught by Hellencamp, to discontinue the vacuum and reposition the apparatus if it is not centered on the cornea, since proper positioning of the corneal flap is critical for refractive surgery, thus producing a device and method such as claimed.

Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) and the admitted prior art of the proper positioning of the corneal flap being critical for refractive surgery as applied to claims 1, 11, and 12 above, and further in combination with Curtin. Curtin teaches the use of adjustment arms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ adjustment arms on the device

of L'Esperance (EP '127), since these can be used to adjustably position the device, which is necessary due to the fact that eyes of different individuals will be in different relative locations, thus producing a device and method such as claimed.

Claims 3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in combination with Curtin or L'Esperance (EP '127), either of these in combination with the admitted prior art of the proper positioning of the corneal flap being critical for refractive surgery, as applied to claims 1, 11, and 12 above, and further in combination with Curtin and Clark et al. Curtin teaches the use of translation rods and adjustment knobs to allow the adjustment in 3 dimensions of an ophthalmic surgical instrument. Clark et al teach employing X- and Y-axis adjustment mechanisms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ the X- and Y-axis adjustment mechanisms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can be used to position the device, or alternatively to employ the modified tissue/vacuum interface of L'Esperance (EP '127) or Hellenkamp in the device of Clark et al, since Clark et al provide no details of this aspect of the device, and in either case to provide the adjustment knob and rod configurations disclosed by Curtin, since Clark provides no details of the manner in which the translational adjustment is effected, thus producing a device and method such as claimed.

Claims 5/3/1, 5/3/2, 6/4/3/1, 6/4/3/2, 9/7/4/3/1, 9/7/4/3/2, 10/8/7/4/3/1, 10/8/7/4/3/2, 17, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp in combination with Curtin and Clark et al and the admitted prior art of the proper positioning of the corneal flap being critical for refractive surgery, as applied to claims

3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18, and 19 above, and further in combination with Olson et al. Olson et al teach the old and well known mechanical expedient of employing set screws to hold two elements in a fixed relation to each other while performing corneal surgery. It would have been obvious to the artisan of ordinary skill to employ docking screws, since these allow the fixation of devices in the adjustment mechanisms, of the combined devices and methods of L'Esperance (EP '127) or Hellenkamp in combination with Curtin and Clark et al, since these can be used to fix the devices, relative to each other during coreal surgery, as taught by Olson et al, thus producing a device and method such as claimed.

Applicant's arguments filed June 25, 2010 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/
Primary Examiner, Art Unit 3769